

REMARKS

I. Specification Amendments

In the specification, Trademarks have been identified where appropriate.

II. Claim Amendments

Support for new claims 12-20 can be found in the specification and claims as originally filed.

New claim 12 can find support for example on page 6 (paragraphs 9 & 35), pages 8-9 (paragraph 18), page 9 (paragraph 20) and page 10 (paragraph 25).

New claim 13 can find support for example on pages 8-9 (paragraph 18).

New claim 14 can find support for example on page 6 (paragraph 37).

New claim 15 can find support for example on page 12 (paragraph 31).

New claim 16 can find support for example on pages 3-4 (paragraph 15).

New claim 17 can find support for example on page 4 (paragraph 16).

New claims 18-20 can find support for example on page 13 (paragraph 35).

No change of inventorship are necessitated by these amendments.

III. Sequence Rules

Applicants herewith submit a substitute Sequence Listing, and CRF.

The Sequence Listing has been modified to better recite the nomenclature of the specification and to incorporate the identified substitutions.

IV. Rejection of Claims 9 and 10 under §101

Claims 9 and 10 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

V. Rejection of Claims 1-3 and 6-11 under §112 first paragraph

Claims 1-11 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

VI. Rejection of Claims 9 - 10 under §112 second paragraph

Claims 9 and 10 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

VII. Claims 1-3 and 6-11 rejected under §102(b)

Claims 1-11 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

The inventors of the present invention have discovered that treatment of certain hormonal-dependent cancers with therapeutic hormonal agents trigger the unexpected increase in growth factor receptor. This subsequently leads to a detrimental transformation of the cancer from hormonal-dependent to a non-hormonal-dependent state. The inventors further discovered that the proper co-administration of a tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity yields the retardation of such detrimental transformation. By the novel method of the claimed invention, combining therapeutic hormonal treatment with the administration of a tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity yields unexpected prolongation of the anti-tumor effect of the hormonal agent.

Applicants wish to point out for the Examiner that the cited art does not teach or suggest the combination of a hormonal agent and a tyrosine kinase inhibitor of the claimed invention. Nor do the cited art references teach or suggest treatment of a hormone-dependent cancer with such agents in combination, or the unexpected results of such combined treatment.

VIII. Claims 1-3 and 6-11 rejected under §103(a)

Claims 1-11 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

The inventors of the present invention have discovered the novel and unobvious method of the claimed invention, combining therapeutic hormonal treatment with the administration of a tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity yields unexpected prolongation of the anti-tumor effect of the hormonal agent.

Applicants wish to point out for the Examiner that the cited art neither alone, nor in combination, teach or suggest the increase in expression of growth factor receptor by the treatment with LH-RH analog therapy, and the superior results achieved in retardation of the transformation of hormone-dependent cancer to non-hormone-dependent cancer by combining inhibition of the increased growth factor receptor with a tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity.

IX. Provisional Double Patenting rejection of Claims 1-11 over US Patent 6,716,863

Claims 1-11 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

The cited patent and the present application are both from commonly owned patent applications with different inventive entities at the time of filing.

Applicants wish to point out that the compound of the present application is not specifically disclosed in the cited US Patent. The cited US Patent does not teach or suggest that transformation of a hormone-dependent cancer to a non-hormone dependent cancer can be suppressed by the administration of a tyrosine kinase inhibitor. Furthermore, the priority date of the present application precedes the filing date of the cited US Patent.

If, however, it is deemed appropriate, Applicants would be prepared to execute the appropriate declaration as required when the claims are in condition for allowance.

X. Provisional Double Patenting rejection of Claims 1-11 over Application 10/620,706

Claims 1-11 have been canceled without prejudice to filing future continuing applications. This rejection is moot.

The cited patent application and the present application are both from commonly owned patent applications with different inventive entities at the time of filing.

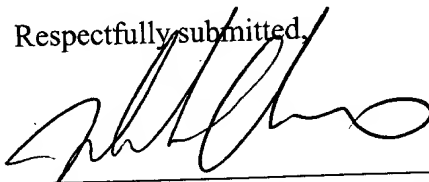
An appropriate declaration will be filed when the claims are in condition for allowance.

Applicants wish to point out that the compound of the present application is not specifically disclosed in the cited Patent application.

XI. Conclusion

Reconsideration of the claims as amended in view of the traverse made above is solicited. Early allowance of the claims is requested. Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, she is respectfully invited to call applicants' attorney.

Respectfully submitted,



Dated: August 31, 2004

(847)383-3372

(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293
Elaine M. Ramesh, Ph.D., Reg. No. 43032
Attorney for Applicants
Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA